K062168
P. 1 of 4

AUG 18 2006

510(k) SUMMARY
NEMOTO KYORINDO
DUAL SHOT – CONTRAST DELIVERY SYSTEM

DATE 510(k) SUMMARY PREPARED: March 24, 2006

OFFICIAL CONTACT: Toshio Kanetaka
Director of Technical Center
Nemoto Kyorindo CO., LTD.
2-12-4 Aoki Kawaguchi-shi
Saitama 332-0031, Japan
TEL : +81 48 250 3255
FAX : +81 48 250 3256

CLASSIFICATION NAME(S): Angiographic Injector with Syringe

DEVICE CLASSIFICATION: Class II

COMMON NAME: Powered Injector with Syringe

PROPRIETARY NAME: Contrast Delivery System – Dual Shot Alpha

PREDICATE DEVICE: DUAL SHOT – CONTRAST DELIVERY SYSTEM from NEMOTO KYORINDO K052633

INTENDED USE: The Contrast Delivery System – Dual Shot Alpha is an intravascular injection system intended for the administration of ionic and non-ionic contrast media and saline used in conjunction with computed X-ray tomography (CT).

DESCRIPTION OF DEVICE:

Contrast Delivery System – Dual Shot Alpha is an Angiographic injector that is used in conjunction with X-ray Computed tomography, and is intended for use by doctors, radiologic technologists and other licensed medical practitioners. This device is designed to correspond to the various injection methods of contrast media which were materialized with the appearance of multi-slice CT scanners. The Dual Shot Alpha has two driving parts to deliver contrast media and/or saline, one side is for 50mL, 100mL and 200mL, size syringes, and the other side for 100mL syringes capable for saline flush injection. Syringes are connected to the patient via an intravascular catheter. Dual Shot Alpha consists following components;

- Injector head

Injector head provides accurate, automatic delivery of contrast media by two electromechanically driven actuators. Sterile empty-syringes or pre-filled syringes can be set onto the Injector head. For the sterile empty-syringes, Injector head provides auto-return function to fill the syringe with contrast media or saline. Injector head is composed of operation indicator LED, switches for manual operation, start-switch to start infusion and stop-switch to stop infusion. Injector head detects injection conditions and transmits the Injector head status information to the console.

- Console

The console takes up very little space on a control desk, and consists of TFT LCD display and touch panel interface to set/display various injections set by an operator. The operator can set injection pressure, time, volume, flow rate and a patient examination region of interest.

- Power Supply

The power supply is intended for placement on the floor around the console of a CT scanner. The power supply consists of a transformer and appliance inlet, as a provide power source to the injector head and console.

- Options

□ Hand Switch

Hand Switch is connected to the console and consists of start and stop switches to start/stop injection according to the protocols already set on the console. Hand Switch provides LEDs with an operator to display scan time and injection state.

SUBSTANTIAL EQUIVALENCE:

Contrast Delivery System – Dual Shot Alpha maintains the same intended use as the predicate device. It is intended for the specific purpose of injecting contrast media and saline solution into a patient's vascular system to obtain diagnostic images in X-ray computed tomography (i.e. "CT").

Contrast Delivery System – Dual Shot Alpha consists of three main components like the predicate device: a Injector head, a Console, and a Power Supply. Both the Dual Shot Alpha and predicate device consist of the same or substantially equivalent materials and technology. They are motor driven, electromechanical devices that are controlled by software.

Below is a table that compares the predicate device to the proposed Contrast Delivery System – Dual Shot Alpha.

Feature	**Proposed Device: Contrast Delivery System – Dual Shot Alpha**	**Predicate Device: DUAL SHOT – CONTRAST DELIVERY SYSTEM**
Intended Use	The Contrast Delivery System – Dual Shot Alpha is an intravascular injection system intended for the administration of ionic and non-ionic contrast media and saline used in conjunction with computed x-ray tomography (CT).	same
Single or Dual Syringe System	Dual syringe model	Same
Information Display	Color LCD	Same
Programming Keys	Non-dedicated keys – software determined	Same
Touch Screen	Yes	Same
Multi-Phase	1-5 Phases per injection	Same
Arming Modes	Single	Same
Protocol Storage Capability	125 protocols	Same
Hold Capability	Until user operate.	Same
Scan Delay	1 – 300 seconds	Same
Safety Stop Mechanism	Multi layered software stops with backup monitoring.	Same
Syringe System	A-head: 200mL or 100mL syringe B-head: 100mL syringe	A-head: 200mL or 100mL syringe B-head: 50mL syringe
Programmed Volume	A-head: 1 to 200mL or 1 to 100mL (depending on syringe size) B-head: 1 to 100mL	A-head: 1 to 200mL or 1 to 100mL (depending on syringe size) B-head: 1 to 50mL
Volume Remaining Readout	Graphic and numeric on LCD	Same
Fill Rate	Variable up to 10mL /sec	Same
Flow Rate	0.1mL/sec to 10mL/sec	Same
Programmable Pressure Limit	Settable from 10 to 300PSI	Same
Pause	Programmable – 1 sec to 300 seconds in 1sec increments	Same
Autofill	Fill rate 1.5mL/sec	Same
Retract Control	No	Same
Remote Start Switch	Yes	Same
Pressure Graph	Yes	Same
Syringe Sensing	Yes	Same
Test Injection	Yes	Same
Syringe Heat Maintainer	Yes	Same

PERFORMANCE DATA:

No performance standards have been established for Angiographic injectors under section 514 of the FD&C Act.

Contrast Delivery System – Dual Shot Alpha has been tested in conformance with the following recognized standards, and is substantially equivalent to the predicate device:

IEC60601-1 (1988) Medical Electrical Equipment, Part 1: General Requirements for Safety - This is the general standard for medical electrical equipment
IEC60601-1-1 (2000) Medical electrical equipment - Part 1-1: General requirements for safety - Collateral standard: Safety requirements for medical electrical systems
IEC60601-1-2 (2001) Medical electrical equipment - Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests
IEC60601-1-4 (1996) Medical electrical equipment - Part 1-4: General requirements for safety - Collateral Standard: Programmable electrical medical systems
ISO13485 (2003) Medical devices - Quality management systems - Requirements for regulatory purposes
ISO14971 (2000) Medical devices – Application of risk management to medical devices

Biocompatibility testing has not been performed since Contrast Delivery System – Dual Shot Alpha does not include a sterile syringe.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 8 2006

TUV Rheinland of North America, Inc.
c/o Ms. Tamas Borsai
12 Commerce Road
Newton, CT 06470

Re: K062168
Contrast Delivery System – Dual Shot Alpha
Regulation Number: 21 CFR 870.1650
Regulation Name: Angiographic Injector and Syringe
Regulatory Class: II
Product Code: DXT
Dated: July 26, 2006
Received: July 31, 2006

Dear Ms. Borsai:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

FOR Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K062168

Device Name: Contrast Delivery System – Dual Shot Alpha

Indications For Use:

The Contrast Delivery System – Dual Shot Alpha is an intravascular injection system intended for the administration of ionic and non-ionic contrast media and saline used in conjunction with computed X-Ray tomography (CT).

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K062168